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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,067	07/03/2003	David Lewis	239770US0DIV	3508

22850 7590 10/11/2007

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EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
10/11/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/612,067	LEWIS ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-28,32,33,37-40 and 44-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-28, 32-33, 37-40 and 44-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/29/07 has been entered.

Receipt is acknowledged of the Amendments and Remarks filed on 06/26/07. Claims 24, 32 and 39 have been amended and claims 29-31, 34-36 and 41-43 have been cancelled. No new claims have been added. Accordingly, claims **24-28, 32-33, 37-40 and 44-48** remain pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24, 26-27, 32, 38-39 and 44-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Jager et al (WO 9413262).

Jager et al teach stabilized medicinal aerosol solution formulations comprising medicaments that degrade or decompose by interaction with solvents or water, an HFC propellant, a cosolvent and an acid (see abstract). Most preferred medicaments for use in the said aerosol solution formulations include steroids (see page 8, lines 1-2). The suitable cosolvents in clued ethyl alcohol, polyethylene glycol, glycerol, etc. Most preferred cosolvent is **ethanol** (see page 9, line 17 to col. 10, line 11). The disclosed formulations contain an acid to prevent degradation. Suitable acids include ascorbic acid and **citric acid**. Claim 21 discloses a formulation comprising from 0.0039 to 27 mg/ml (page 10, lines 17-32). The formulations also contain excipients such as antioxidants including ascorbic acid and tocopherol (see page 6, lines 10-12). Ascorbic acid is disclosed at a concentration range of 0.0045 to 5.0 mg/ml (see Table 2 and claim 20).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 28, 33, 40 and 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jager et al (WO 9413262) in view of Tzou et al (5,776,433).

Jager et al, discussed above, lacks disclosure on specific steroids such as flunisolide and beclomethasone dipropionate.

Tzou et al teach aerosol formulations in a solution form comprising flunisoilde and an HFA propellant (see abstract). The formulations also contain ethanol as a solvent (col. 2, lines 50-55).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the general formulations of Jager et al to have looked in the art for specific steroids as taught by Tzou et al with a reasonable expectation of success. Furthermore, optimizing the concentration range of antioxidant in a pharmaceutical formulation to adjust or improve the stability of the formulation is within the capabilities of a person of ordinary skill in the art. In other words, the claims would have been obvious because a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.

Claims 25, 37 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jager et al (WO 9413262) in view of Rubin (4,584,320).

Jager et al, discussed above, discloses addition of antioxidants such as ascorbic acid and tocopherol, but lacks specific disclosure on ascorbyl palmitate.

Rubin teaches a method of treating asthma employing formulations comprising ETA, suitable carrier and suitable antioxidants (see abstract). Suitable antioxidant include butylated hydroxytoluene, butyl hydroxyanisole, ascorbic acid, ascorbyl palmitate and tocopherol or combinations thereof (see col. 3, lines 38-53).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the general formulations of Jager et al to have looked in the art for other suitable antioxidants as taught by Rubin with a reasonable expectation of success. In other words, the claims would have been obvious because a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.

Claims 24, 26-27, 32, 38-39 and 44-45 are rejected under 35 U.S.C 103(a) as being unpatentable over GB 1525181 in view of Shultz (WO 9206675).

GB 1525181 teach formulations comprising flunisolide and their use in treating respiratory disorders. It is disclosed that flunisolide as an atomisable solution in a pharmaceutically acceptable solvent suitable for nasal or inhalation administration (col. 4, lines 43-60). A liquid solution of flunisolide is readily dispensed from a flexible squeeze bottle or other atomizing device. The composition comprises about 0.001 to 0.1% flunisolide, 0 to 50% of a suitable organic solvent and 0 to 5% suitable excipients.

Suitable solvents include ethanol and suitable excipients include antioxidants such as citric acid, BHA, BHT, etc (see col. 6, line 44 to col. 7, line 16). GB 1525181 lacks disclosure on specific HFA propellants.

Schultz teach aerosol solution formulations comprising beclomethasone dipropionate, ethanol and a propellant selected from HFA 134a and HFA227. the said formulations are suitable for pulmonary or nasal administration (see page 2, line 19 to page 3, line 40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the general formulations of GB 1525181 to have looked in the art for other suitable propellants as taught by Schultz with a reasonable expectation of success. In other words, the claims would have been obvious because a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **24-28, 32-33, 37-40 and 44-48** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,713,047 in view of Rubin (4,584,320). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant Application and the claims of the U.S. Patent are essentially drawn to the same formulations, inhalers and method of treating. The difference is that the instant claims require addition of an antioxidant. Rubin teaches addition of an antioxidant to formulations that are subject to oxidation. Thus it would have been obvious to one of ordinary skill in the art to have implemented the teachings of Rubin and have added the antioxidants in the said formulations of the instant application.

Claims 24-28, 32-33, 37-40 and 44-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/612,072 (US 20040096399). Although the conflicting claims are not identical, they are not patentably distinct from each other because both Applications contain claims drawn to an aerosol formulation comprising a corticosteroid,

a propellant, a cosolvent and an antioxidant. Both Applications also have claims drawn to a pressurized metered dose inhaler comprising the said formulation and a method of treating respiratory disorders by administration of the said formulation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **24-28, 32-33, 37-40 and 44-48** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application Nos. 10/275,891 (US 20030190289); 10/435,032 (US 20030206870); 10/435,354 (US 20030190287); 10/766,857 (US 20040184993) in view of Rubin (4,584,320). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant Application and the claims of the co-pending Applications are essentially drawn to the same formulations, inhalers and method of treating. The difference is that the instant claims require addition of an antioxidant. Rubin teaches addition of an antioxidant to formulations that are subject to oxidation. Thus it would have been obvious to one of ordinary skill in the art to have implemented the teachings of Rubin and have added the antioxidants in the said formulations of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed on 06/26/07 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian
Patent Examiner
September 28, 2007